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## BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 4062007

Application Number: 09/879,433

Filing Date: June 12, 2001

Appellant(s): CROWLEY, ROBERT J.

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Brandon C. Stallman For Appellant

**EXAMINER'S ANSWER** 

This is in response to the appeal brief filed January 10, 2007, which was filed in response to the remand from the Board of Appeals mailed May 5, 2006. The remand required the examiner to

mail out corrected 1449s clearly indicating the consideration or non-consideration of all items listed thereon, and further required the examiner and the applicant to resubmit their respective papers, amended to specifically indicate the grounds of rejection of claim 26. In the office action mailed May 21, 2004, page 2 contains a rejection of a number of claims including claim 25 (see the ultimate paragraph on the page numbered 2 of that office action). In the paragraph bridging the pages numbered 3 and 4 there is also a rejection of a number of claims, among them, a claim identified as claim 25, which rejection specifically states "Spears et al teach employing a balloon enclosing the light emitters and placing a fluid therein to transfer heat". Given that claim 26 recites "transporting fluid to the light device to dissipate heat generated by the light device"; it is clear that the rejection bridging the pages numbered 3 and 4 of the office action mailed May 21, 2004 was intended to be applied to claim 26 and that the recitation of claim 25 therein is an obvious typographical error, given that claim 26 is clearly indicated as among the rejected claims on the PTOL-326 form accompanying the office action mailed May 21, 2004. Thus no new grounds of rejection has been applied.

#### (1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

#### (2) Related Appeals and Interferences

A statement identifying the related appeals and interferences, which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

#### (3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

#### (4) Status of Amendments After Final

No amendments after file have been filed.

### (5) Summary of Invention

The summary of invention contained in the brief is correct.

### (6) Issues

The appellant's statement of the issues in the brief is correct.

## (7) Grouping of Claims

Appellant's brief includes a statement that claims 14-30 and 37-40 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

Appellant's brief includes a statement that claims 31 and 32 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

Appellant's brief includes a statement that claims 33-36 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

#### (8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

#### (9) Prior Art of Record

The copy of the appealed claims contained in the Appendix to the brief is correct. The following is a listing of the prior art of record relied upon in the rejection of claims under appeal.

Number	Name	Date
3,970,394	Stanton	July 20, 1976
4,662,733	Feinbloom	May 5, 1987
4,799,479	Spears	January 24, 1989

5,053,033	Clarke	October 1, 1991
5,405,369	Selman et al	April 11, 1995
5,617,163	Ohtake	April 1, 1997
5,814,041	Anderson et al	September 29, 1998
5,899,882	Waksman et al	May 4, 1999

### (10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 14-18, 21, 22, 25, 27, 28, 39 and 40 are rejected under 35 U.S.C. Selman et al in combination with Clarke. Selman et al teach a method such as claimed except for the use of s flash lamp including providing a light device (see Figure 1, elements 28, 22, 24 and 26, see column 8, line 65 to column 9, line 21, see especially column 9, line 17-18 wherein the source can be a laser, LED device, or lamp); the device is inserted inside the body (see Figure 1, bladder 10 (column 9, lines 10-13); the source can produce ultraviolet radiation (see column 6, lines 35-40); and the mucosal lining of the transplanted tissue is destroyed (see column 3, lines 36 to 59); a variety of tissues can be treated with the method (see column1, lines 22 to 43). Clark teaches a tissue ablation method wherein a light device is introduced into the body (See Figure 3B and column 4, line 65 to column 5, line 5). Clarke also teaches that the light can be produced by a variety of sources including lasers and flash lamps (see column 2, lines 51-62). It would have been obvious to the artisan of ordinary skill to employ the flash lamp of Clarke as the source in the method of Selman et al, since this is equivalent to the laser as taught by Clarke and since Selman et al teach that any of a variety of light sources can be used, thus providing a method such as claimed.

Claims 14, 19 and 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al in combination with Clarke. Anderson et al teach destroying the uterine lining (see column 2, lines 29-34); discloses that ultraviolet light can be used and that various tissues can be treated (see column 2, lines 41-65); the method is accomplished using a photosensitive dye (see column 3, lines 4-8); and controlled or uniform illumination is desirable (see column 5, line 30-46); and the light source is described as "usually a laser fiber" (see column 5, lines 24-29), therefore can include sources other than lasers. The teaching of Clarke is as set forth above. It would have been obvious to the artisan of ordinary skill to employ a flash lamp as the light source in the method of Anderson et al, since these are equivalent to lasers as taught by Clarke thus producing a method such as claimed.

Claims 20, 23, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Selman et al in combination with Clarke as applied to claims 14-18, 21, 22, 25, 27, 28, 39 and 40 above, and further in view of Waksman et al. Waksman et al teach the applicability of treatments of blood vessels and bladder surfaces to the surface of the urethra (see column 2, line 59 to column 3, line 15 and column 37, lines 18-21. Thus it would have been obvious to the artisan of ordinary skill to employ the combined method of Clarke and Selman et al on any of the tissues of Waksman et al, since these are equivalents, as taught by Waksman et al, thus producing a method such as claimed.

Claims 26, 29, 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Selman et al in combination with Clarke as applied to claims 14-18, 21, 22, 25, 27, 28, 39 and 40 above, and further in view of Waksman et al and Spears et al. The teachings of Waksman et al and the motivations for combination thereof are as set forth above. Spears et al teach employing a balloon enclosing the light emitters and placing a fluid therein to transfer heat (see column 4,

lines 12-29). It would have been obvious to the artisan of ordinary skill to employ the teachings of Waksman for the reasons set forth above and to employ the balloon and fluid of Spears et al, since this will better enable the energy to reach the tissue to be treated, thus producing a method such as claimed.

Claims 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al in combination with Clarke as applied to claim 14 above, and further in view of Ohtake. Ohtake teach the use of a lenticular surface which take the form of a Fresnel lens (see Figure 3 and column 5, lines 10-17) with a flash lamp. It would have been obvious to the artisan of ordinary skill to employ a lenticular surface in the method of Anderson et al in combination with Clarke, since this would provide a more even distribution of light (see Ohtake, column 5, lines 23-25), thus producing a method such as claimed.

Claims 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Selman et al in combination with Clarke as applied to claim14 above, and further in view of Feinbloom. Feinbloom teaches a flash lamp circuit that uses a transformer to step up the voltage. It would have been obvious to the artisan of ordinary skill to employ a transformer to step up the voltage, since this provides a bright light (see column 2, lines 36-64), as taught by Feinbloom, and is standard in flash lamp activating circuits, official notice of which has already been taken, thus producing a method such as claimed.

Claims 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Selman et al in combination with Clarke and Feinbloom as applied to claims 33 and 34 are above, and further in view of Stanton. Stanton teaches the use of a foil as a triggering electrode for a flash lamp. It would have been obvious to the artisan of ordinary skill to employ the triggering

electrode as taught by Stanton, since this would help provide a more evenly distributed flash (see column 2, lines 19-25), thus producing a method such as claimed.

### (11) Response to Argument

#### 1.1 The combination is not taught away from

Applicant argues that Selman et al and Clarke cannot be combined as each teaches away from the combination, as Clarke describes using ultraviolet light to destroy the underlying smooth muscle cells while sparing the endothelium. The examiner notes the argument and adds that Clarke also teaches that the tissue effects of the absorption of the light is interchanged whether a laser or a flash lamp is used. Selman et al, as acknowledged by applicant, alters the absorbing properties of the tissue that is to be treated by administering a photosensitive dye that absorbs the radiation. Applicant argues that because Selman et al use a dye and Clarke does not "one skilled in the art would not automatically associate the two as interchangeable techniques or look in one approach for modification in the other" (Brief on Appeal, page 7, last full sentence). However, the examiner is not suggesting that the two techniques are interchangeable. The examiner is merely noting that the ordinarily skilled surgeon would understand that the absorption of ultraviolet light by the photosensitizing dye in this method of Selman et al would be the same regardless of he particular source of the ultraviolet light, this is taught by Selman et al at column 9, lines 17-18. Thus the ordinarily skilled surgeon, when choosing among the conventional light sources taught by Selman et al column 7, lines 21-28, would look to any light application method, regardless of the tissue treated or the mechanism of action, since the mechanism of action in the method of Selman et al is the dye, when choosing a particular source. Applicant then asserts that the combination suggested by the examiner would change the principles of operation of the references, citing *Ratti* (Brief on Appeal sentence bridging pages 7

and 8). As set forth above, the principle of operation of Selman is preserved regardless of the ultraviolet source employed: the dye is absorbed into the tissue to be destroyed, the dye absorbs the light, and the tissue is destroyed, thus no redesign is required as was in *Ratti*. Thus appellant reliance thereon is misplaced.

Lastly appellant argues that since Clarke seeks to preserve the layer Selman et al destroy one would not use Clarke's flash lamp (Brief on Appeal, pages 8, first full paragraph). However, since the absorption of the light in Selman et al is controlled by the photosensitive dye, one of ordinary skill would not be dissuaded from employing the flash lamp of Clarke, since it is wavelength that determines absorption by the dye (see Selman et al column 6, lines 19-22) and not the particular source that produces the wavelength.

## 1.2 <u>Teachings of the combination compared to the claim language</u>

Selman et al teach irradiating tissue with ultraviolet light to trigger photodynamic dye in the tissue to absorb the radiation, and the absorption of light by the photodynamic dye is dependent on the wavelength of the light, which can be produced by a variety of sources. Clark teaches a tissue ablation method wherein a variety of ultraviolet sources may be used including lasers (one of the sources particularly mentioned by Selman et al) and flash lamps. Thus the combination, which includes the use of a photosensitive dye by Selman et al does read on the claim language of claim 14, etc. which does not preclude the use of dyes. In fact the use of a dye is called for specifically in claim 27 as are light activated drugs in claim 28, both dependent form claim 14.

# 2. The Combination of Anderson et al and Clarke reads on the claims to which it is applied

Appellant's arguments regarding this combination are essentially the same as those directed to the combination of Selman et al and Clarke: that different tissues are targeted.

However, as above, Anderson et al teach tissue ablation by photodynamic therapy by illuminating a photosensitizer (see column 7, lines 19-22), wherein the photosensitive dye is administered to the tissue to be treated (see Column 2 lines 23 to 28), wherein the device can employ ultraviolet light (see column 2 lines 60 to 65), wherein the light source is "usually a laser fiber" (see column 5, line 26), which is a clear indication that other sources can be used. Clarke as above teaches the equivalence of flash lamps and lasers as sources of ultraviolet light. Thus as above, the combination is proper, since it is merely the source of the light which is derived from the Clarke reference and since the tissue destruction is wrought by the absorption of light by the photosensitive dye, the fact that Clarke targets a different tissue layer for destruction does not teach away from the combination.

#### 3. Propriety of the combination of Selman et al, Clarke and Waksman et al

Appellant attacks the combination of Selman et al, Clarke and Waksman et al in the basis of the alleged deficiencies of the combination of Selman et al and Clarke. As set forth above, the combination is not deficient, thus the combination including Waksman et al is similarly paper and reads on the claims to which it is applied

## 4. <u>Propriety of the combination of Selman et al, Clarke, Waksman et al and Spears</u>

Again appellant attacks this combination on the basis of the alleged deficiencies of the base combination. As already set forth above, the base combination is not deficient, thus the combination including Waksman et al and Spears is similarly not deficient.

#### 5. Propriety of the combination of Anderson et al, Clarke, and Ohtake

Appellant argues that as the device of Ohtake is not a medical device, there is no suggestion for the combination thereof with Anderson et al and Clarke. However, Anderson et al makes clear the need for uniform illumination (see the last sentence of the Abstract and column

3, line 65 to column 4, line 32) when seeking to produce such uniform intensity, the surgeon of ordinary skill would of necessity look to arts where producing uniform intensity of illuminations is important, such as the arts of illumination and photography. The Ohtake reference, discloses a photographic illuminator, which employs a flash lamp and a Fresnel lens. The Fresnel lens is employed to produce a uniform instantly in the direction of light propagation (see column 5, lines 23-32). Thus the motivation to combine Ohtake derives not only from Ohtake, but from Anderson et al as well.

## 6. Propriety of the combination of Selman et al, Clarke and Feinbloom

Appellant argues that Feinbloom neither provide a suggestion for combination nor a discussion as to why the voltage should be stepped up in an *in vivo* tissue ablation method. As to the latter argument, Selman et al actually supplies discussion, noting that not only must the wavelength, but also the intensity be sufficient to activate the photosensitizer (see the Abstract). As to the former argument Feinbloom teaches that the high voltage ionizes the gas in the flash tube allowing high intensity current to flow, causing a bright discharge (see column 2, line 36-64, especially lines 53-64) thus it is the high voltage which provides the high intensity. Further the use of such transformers is standard in flash lamp activating circuits, which has been officially noticed in the Final Rejection, and has not been seasonably challenged by Appellant. Thus the combination is proper and reads on the claims.

## 7. Propriety of the combination of Selman et al, Clark, Feinbloom and Stanton

Appellant argues that Stanton does not remedy the deficiencies of the base combination.

However, as set forth above the base combination is not deficient thus, this argument must fail.

One would be motivated to employ the foil electrodes of Stanton because this provides a more

evenly distributed flash, thereby enabling the required intensity level to also be evenly distributed.

It is the examiner's firm opinion that the appealed claims are not patentable for the reasons argued above. Appellant has presented no convincing argument as to why the rejections set forth above are not obvious or proper. Therefore, it is respectfully submitted that the finalk rejection be affirmed

Respectfully submitted,

DAVID M. SHAY PRIMARY EXAMINER GROUP 330

David Shay April 7, 2007

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